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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,413

02/25/2004

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EXAMINER

LANG, AMY T

ART UNIT

PAPER NUMBER

3731

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DELIVERY MODE

08/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,413	<b>Applicant(s)</b> KIM, DUCKSOO	
	<b>Examiner</b> AMY T. LANG	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Species B in the reply filed on 04/30/2008 is acknowledged.
2. Claims 1-5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/30/2008.

### ***Claim Objections***

3. **Claim 8** is objected to because of the following informalities: line 3 of claim 8 recites "volumetric shaft" where "shaft" should be replaced with "sheath". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. **Claims 6-18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites a "catheterless" introducer assembly. However, the introducer assembly comprises a hollow shaft with internal means for inflating a distal balloon.

Therefore, the shaft comprises a lumen which inherently produces a catheter. Since the introducer assembly comprises a catheter shaft, the claim reciting a catheterless introducer is rendered indefinite. Claims 7-18 are dependent on claim 6 and therefore are also indefinite.

6. **Claim 7** contains the trademarks/trade names HeartMate, Thoratec, Novacor, MicroMed, Arrow LionHeart, and Levitronics. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademarks or trade names cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademarks/trade names are used to identify/describe ventricular assist devices and, accordingly, the identification/description is indefinite.

7. **Claims 11-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-13 recite "said linking connector" where it is unclear if the connector refers to the inflow or outflow connector.

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8. **Claims 14-17** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-17 recite "said conduit" where it is unclear if the conduit refers to the inflow or outflow conduit.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 6-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. (US 6,387,037 B1) in view of Kim (US 5,676,670).

With regard to **claim 6**, Bolling et al. (hereinafter Bolling) discloses a method for surgically attaching a ventricular device to the circulatory system of living subject (see entire document). The method comprises obtaining a ventricular assist device having a

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housing, a pump (32), and a power source (44) (Figure 2; column 11, lines 40-42). The pump comprises an inlet (34) and outlet (36) for connection to an inflow conduit (50) and an outflow conduit (52) (column 10, lines 7-12; column 11, lines 62-65). Linking connectors (68, 70) are connected to the inflow and outflow conduits to access and direct blood flow (column 13, lines 1-27). As shown in Figures 3 and 7, the connectors are suitable dimensions for passage through an aperture and are deformable.

Bolling further teaches wherein the ventricular assist device is inserted into a patient using a catheter introducer assembly (column 16, lines 50-53). The connectors and conduits are then assembled as shown in Figures 2 and 3.

Although Bolling teaches a catheter introducer for entry into the patient's vessel, Bolling does not specifically disclose the catheter introducer.

Kim teaches that catheter introducers are well known in the art and used for a variety of procedures. The specific catheter disclosed by Kim comprises an elongated shaft (134) connected to a perforating headpiece (120) (Figure 9). A handle is disclosed in Figures 1 and 2 at the proximal end of the shaft. Additionally, the very proximal end of the shaft also overlaps a handle. As shown in Figures 14 and 15, Kim discloses an internal conduit for controlling the perforating headpiece that clearly overlaps the instantly claimed conduit controlling means (column 14, line 39 through column 15, line 67). The assembled catheter introducer, including an external sheath (2) is disclosed in Figure 30. This catheter introducer is capable of delivering an inflow or outflow conduit by placing the conduit on the sheath and removing the sheath to release the conduit (Figures 32-40).

Since Bolling does not specifically disclose the introducer catheter and Kim teaches that such catheters are well known in the art and specifically discloses one that is capable of delivering a conduit, it would have been obvious at the time of the invention for Bolling to utilize the catheter introducer of Kim. This would allow an inflow or outflow conduit to be inserted within a patient and prepare for a sutureless juncture.

With regard to **claim 7**, Bolling teaches that a rotary or any other type of pump may be used (column 6, lines 50-56). Therefore, since Bolling is open to the pump utilized, it would have been obvious to one of ordinary skill in the art at the time of the invention for Bolling to utilize the instantly claimed pumps.

With regard to **claim 8**, the sheath, as shown in Figure 32 of Bolling, comprises a volumetric component, is sized for an on-demand placement, is substantially annular, and is adapted for providing protective positioning to the shaft.

With regard to **claim 9**, as shown in Figure 15 of Kim, the shaft is hollow.

With regard to **claim 10**, the conduit controlling means of Kim comprises an inflatable and deflatable balloon appliance (column 15, lines 19-55).

With regard to **claims 11 and 12**, Bolling does not disclose the material of the linking connectors. However, Nitinol is a well known alloy that is beneficial by allowing a component to be inserted into a patient in a compacted configuration and then return to its preset expanded configuration at the target site. Therefore, it would have been obvious at the time of the invention for the linking connectors to comprise Nitinol, a shape-memory alloy.

With regard to **claim 13**, Bolling teaches the linking connectors as a wire meshwork (Figure 6).

With regard to **claims 14 and 15**, the inflow and outflow conduits of Bolling are further disclosed as comprised of a synthetic material or naturally occurring material (column 11, line 62 through column 12, line 3).

With regard to **claim 16**, Bolling discloses that no valves are necessary within the conduits (column 10, lines 16-17). Therefore, Bolling teaches that valves are utilized with ventricular devices and that valves could potentially be used with the specific ventricular device of Bolling. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for Bolling to utilize a valve within the conduits.

With regard to **claim 17**, Bolling discloses end caps placed around the connectors, which clearly overlaps the instantly claimed stabilizing rings (column 13, lines 64-66).

With regard to **claim 18**, Bolling does not disclose the use of sutures to secure the conduits to the pump.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY T. LANG whose telephone number is (571)272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

08/08/2008

/Amy T Lang/

Examiner, Art Unit 3731

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731